# Multi-Drug 6 Drugs Rapid Test (Oral Fluid)
## Package Insert

**REF DSD-863-D | English**

*A rapid test for the simultaneous, qualitative detection of multiple drugs or drug metabolites in human oral fluid. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.*

**【INTENDED USE】**

The Multi-Drug Rapid Test for OPI/MOP/COC/AMP/OXY/MET/THC/ALC is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in oral fluid at the following cut-off concentrations:

| Test | Calibrator | Cut-off (ng/mL) |
|---|---|---|
| Opiates (OPI/MOP) | Morphine | 40 |
| | 6-Monoacetylmorphine(6-MAM) | 4 |
| Cocaine (COC) | Benzoylecgonine | 30 |
| Amphetamine (AMP) | d-Amphetamine | 40 |
| Oxycodone (OXY) | Oxycodone | 40 |
| Methamphetamine (MET) | d-Methamphetamine | 40 |
| | 3,4-Methylenedioxymethamphetamine(MDMA) | 50 |
| Marijuana (THC) | 11-nor-$\Delta^9$ -THC-9 COOH | 10 |
| **Test** | **Calibrator** | **Cut-off** |
| Alcohol(ALC) | Alcohol | 0.02% |

This assay provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

**【SUMMARY】**

The Multi-Drug Rapid Test is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

**Amphetamine (AMP)**

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, amphetamine can be detected in oral fluid as early as 5-10 minutes following use. [1] Amphetamine can be detected in oral fluid for up to 72 hours after use. [1]

The AMP assay contained within the Multi-Drug Rapid Test yields a positive result when the amphetamine concentration in oral fluid exceeds 40ng/mL.

**Methamphetamine (MET)**

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes following use.[1] Methamphetamine can be detected in oral fluid for up to 72 hours after use.[1]

The MET assay contained within the Multi-Drug Rapid Test yields a positive result when the methamphetamine concentration in oral fluid exceeds 40ng/mL, or the 3,4-Methylenedioxymethamphetamine concentration in oral fluid exceeds 50ng/mL.

**Cocaine (COC)**

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and metabolites benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use.[1] Cocaine and benzoylecgonine can be detected in oral fluid for up to 24 hours after use.[1]

The COC assay contained within the Multi-Drug Rapid Test yields a positive result when the cocaine metabolite in oral fluid exceeds 30ng/mL.

**Opiates (OPI/MOP)**

The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the intravenously or by nasal inhalation. Using an immunoassay cutoff level of 40ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose.[1] Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more prevalently in excreted unmetabolized, and is also the major metabolic product of codeine and heroin.[2]

The OPI/MOP assay contained within the Multi-Drug Rapid Test yields a positive result when the opiates concentration in oral fluid exceeds 40 ng/mL, or the 6-Monoacetylmorphine concentration in oral fluid exceeds 4 ng/mL.

**Marijuana (THC)**

11-nor-$\Delta^9$-tetrahydrocannabinol-9-carboxylic acid ($\Delta^9$-THC-COOH), the metabolite of THC ($\Delta^9$-tetrahydrocannabinol), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.[3] Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use. [3]

The THC assay contained within the Multi-Drug Rapid Test yields a positive result when the $\Delta^9$-THC-COOH concentration in oral fluid exceeds 10 ng/mL.

**Oxycodone (OXY)**

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy.Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone.

The OXY assay contained within the Multi-Drug Rapid Test yields a positive result when the Oxycodone concentration in oral fluid exceeds 40ng/mL.

**Alcohol (ALC)**

Two-thirds of all adults drink alcohol.[5] The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Each individual has specific parameters that affect the level of impairment such as size, weight, eating habits and alcohol tolerance. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions.[6]

**【ASSAY PRINCIPLE】**

The Multi-Drug Rapid Test is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**【ALCOHOL PRINCIPLE】**

The oral fluid Alcohol Rapid Test consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

**【REAGENTS】**

Each test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to corresponding drug.

**【ALCOHOL REAGENTS】**

Tetramethylbenzidine/Alcohol Oxidase (EC 1.1.3.13)/Peroxidase (EC 1.11.1.7)/ Other additives

**【PRECAUTIONS】**

- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Oral fluid is not classified as biological hazard unless derived from a dental procedure.
- The used Device should be discarded according to local regulations.

**【ALCOHOL PRECAUTIONS】**

Test materials that have been exposed to oral fluid should be treated as potentially infectious. Do not use the Oral fluid Alcohol Rapid Test after the expiration date marked on the foil package.

**【STORAGE AND STABILITY】**

Store as packaged in the sealed pouch at 2-30 °C. The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

**【ALCOHOL STORAGE AND STABILITY】**

The Alcohol Rapid Test is to be stored at 2-30 °C in its sealed foil package. If storage temperatures exceed 30°C, the test performance may degrade. If the product is refrigerated, the Oral fluid Alcohol Rapid Test must be brought to room temperature prior to opening the pouch.

**【SPECIMEN COLLECTION AND PREPARATION】**

The oral fluid specimen should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection Device should be used with this assay. Oral fluid collected at any time of the day may be used.

When testing with Alcohol storage of oral fluid specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing.

**【MATERIALS】**

**Materials Provided**

- Test Devices
- ALC color chart (when applicable)
- Package insert

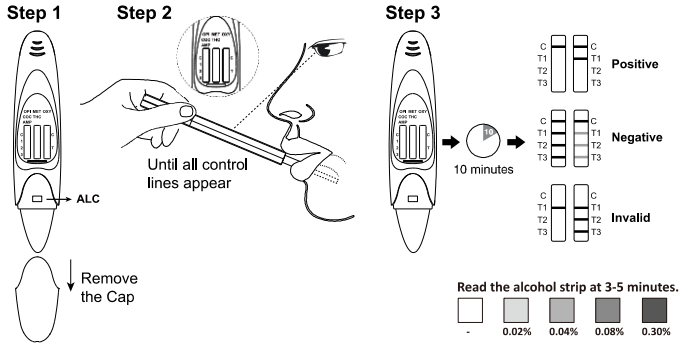
**Materials Required but Not Provided**

- Timer

**【DIRECTIONS FOR USE】**

**Allow the test device, specimen and/or controls to reach room temperature (15-30 °C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.**

1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.
2. Take off the device cap and insert the absorbent wick to the mouth .put it under the tongue to collect oral fluid until the control line appears and then take out the device.
3. Place the test device on a clean and level surface.
4. Read the drug test result at **3-10 minutes.** See illustration below.
   If all lines are clearly visible at 3 minutes or sooner, then the test can be interpreted as negative and discarded. If any lines are not visible at 3 minutes, then the test should be re-read at 10 minutes.
5. **Alcohol indicator, when applicable, the result should be read at 3-5 minutes**. Compare the color of the reaction pad with the color chart provided separately/on foil pouch to determine the relative oral fluid alcohol level.




**【INTERPRETATION OF RESULTS】**

(Please refer to the previous illustration)

**NEGATIVE:* A colored line appears in the control region (C) and another colored line appears in the test region (T)**. This negative result means that the concentrations in the oral fluid sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the Test regions (T) may vary. The result should be considered negative whenever there is even a faint line.

**POSITIVE: A colored line appears in the control region (C) and no line appears in the test region (T).** The positive result means that the drug concentration in the oral fluid sample is greater than the designated cut-off for a specific drug.

**INVALID: No line appears in the control region (C).** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test device. If the result is still invalid, contact your manufacturer.

**【ALCOHOL STRIP INTERPRETATION】**

**Positive:** The **Oral Fluid Alcohol Rapid Test** will produce a color change in the presence of oral fluid alcohol. The color will range from light blue color at 0.02% relative oral fluid alcohol concentration to a dark blue color near 0.30% relative oral fluid alcohol concentration. Color pads are provided within this range to allow an approximation of relative oral fluid alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

**NOTE:** The Oral fluid Alcohol Rapid Test is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in oral fluid.

**Negative:** When the oral fluid Alcohol Rapid Test shows no color change this should be interpreted as a negative result indicating that alcohol has not been detected.

**Invalid**: If the color pad has a blue color before applying oral fluid sample, do not use the test.

**NOTE:** A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with oral fluid. The test is not reusable.

**【QUALITY CONTROL】**

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

**【LIMITATIONS】**

1. The Multi-Drug Rapid Test provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) is preferred confirmatory methods. [4]
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

**【ALCOHOL LIMITATIONS】**

1. The **Oral Fluid Alcohol Rapid Test** is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the **Oral Fluid Alcohol Rapid Test**. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
2. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

## 【PERFORMANCE CHARACTERISTICS】

### Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ±50% cut-off, ±25% cut-off and 300% cut-off and tested with the Multi-Drug Rapid Test. The results are summarized below.

| Drug Concentration Cut-off Range | AMP 40 | | MET 40 | | THC 10 | | COC 30 | | OPI 40 | | OXY 40 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 |
| -50% Cut-off | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 |
| -25% Cut-off | 27 | 3 | 28 | 2 | 27 | 3 | 27 | 3 | 27 | 3 | 27 | 3 |
| Cut-off | 15 | 15 | 16 | 14 | 12 | 18 | 15 | 15 | 13 | 17 | 20 | 10 |
| +25% Cut-off | 7 | 23 | 6 | 24 | 8 | 22 | 8 | 22 | 7 | 23 | 4 | 26 |
| +50% Cut-off | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 |
| 300% Cut-off | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 |

### Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the Multi-Drug Rapid Test identified positive results at a read time of 10 minutes.

| Compound | ng/mL | Compound | ng/mL |
|---|---|---|---|
| **Amphetamine (AMP40 )** | | | |
| d-Amphetamine | 40 | ß-Phenylethylamine | 25,000 |
| d/l-Amphetamine | 100 | l-Amphetamine | 25,000 |
| p-Hydroxyamphetamine | 100 | Methoxyphenamine | 12,500 |
| (+)3,4-Methylenedioxyamphetamine (MDA) | 100 | Tryptamine | 12,500 |
| **Methamphetamine (MET40 )** | | | |
| d-Methamphetamine | 40 | Procaine | 2,000 |
| Fenfluramine | 60,000 | (1R,2S) - (-) Ephedrine | 400 |
| p-Hydroxymethamphetamine | 400 | Ephedrine | 400 |
| Methoxyphenamine | 25,000 | Benzphetamine | 25,000 |
| 3,4-Methylenedioxymethamphetamine (MDMA) | 50 | Mephentermine | 1,500 |
| l-Phenylephrine (R)-(-)-Phenylephrine | 6,250 | | |
| **Marijuana (THC10 )** | | | |
| 11-nor-$\Delta^9$ -THC-9 COOH | 10 | $\Delta^8$ -THC | 6,000 |
| Cannabinol | 12,500 | $\Delta^9$ -THC | 10,000 |
| 11-nor-$\Delta^8$-THC-9 COOH | 10 | | |
| **Cocaine (COC30 )** | | | |
| Benzoylecgonine | 20 | Ecgonine | 1,500 |
| Cocaine | 20 | Ecgonine methyl ester | 12,500 |
| Cocaethylene | 30 | | |
| **Opiates(OPI40)** | | | |
| Morphine | 40 | Norcodeine | 6,250 |
| Codeine | 25 | Normorphine | 25,000 |
| Ethylmorphine | 25 | Nalorphine | 10,000 |
| Hydromorphine | 100 | Oxymorphone | 25,000 |
| Hydrocodone | 100 | Thebaine | 2,000 |
| Diacetylmorphine(Heroin) | 50 | Levorphanol | 400 |
| Oxycodone | 25,000 | 6-Monoacetylmorphine | 4 |
| Morphine 3-β-D-Glucuronide | 50 | | |
| **Oxycodone (OXY40 )** | | | |
| Oxycodone | 40 | Hydromorphone | 10,000 |
| Oxymorphone | 40 | Naloxone | 5,000 |
| Levorphanol | 10,000 | Naltrexone | 5,000 |
| Hydrocodone | 1,500 | | |

### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Multi-Drug Rapid Test when tested with at concentrations up to 100 μg/mL.

| | | |
|---|---|---|
| N-Acetylprocainamide | Ethyl-p-aminobenzoate | Pentobarbital |
| Acetylsalicylic acid | Fenoprofen | Perphenazine |
| Aminopyrine | Furosemide | Phencyclidine |
| Amitryptyline | Gentisic acid | Phenelzine |
| Amobarbital | Hemoglobin | Phenobarbital |
| Amoxicillin | Hydralazine | Phentermine |
| Ampicillin | Hydrochlorothiazide | Promazine |
| L-Ascorbic acid | Hydrocortisone | Promethazine |
| Apomorphine | O-Hydroxyhippuric acid | D,L-Propanolol |
| Aspartame | 3-Hydroxytyramine | D-Propoxyphene |
| Atropine | Ibuprofen | D-Pseudoephedrine |
| Benzilic acid | Imipramine | Quinidine |
| Benzoic acid | Iproniazid | Quinine |
| Bilirubin | (±) - Isoproterenol | Secobarbital |
| (±) - Brompheniramine | Isoxsuprine | Serotonin (5-Hydroxytyramine) |
| Caffeine | Ketamine | Sulfamethazine |
| Cannabidiol | Ketoprofen | Sulindac |
| Chloralhydrate | Labetalol | Temazepam |
| Chloramphenicol | Loperamide | Tetracycline |
| Chlordiazepoxide | Maprotiline | Tetrahydrocortisone 3-acetate |
| Chlorothiazide | Meprobamate | Tetrahydrocortisone 3(β-D-glucuronide) |
| (±) Chlorpheniramine | Methadone | Tetrahydrozoline |
| Chlorpromazine | Methylphenidate | Thiamine |
| Chlorquine | Methyprylon | Thioridazine |
| Cholesterol | Nalidixic acid | D, L-Thyroxine |
| Clomipramine | Nifedipine | Tolbutamine |
| Clonidine | Norcodein | Triamterene |
| Cortisone | Norethindrone | Trifluoperazine |
| (-) Cotinine | D-Norpropoxyphene | Trimethoprim |
| Creatinine | Noscapine | Trimipramine |
| Diazepam | D,L-Octopamine | L-Phenylephrine |
| Diclofenac | Oxalic acid | D, L-Tryptophan |
| Diflunisal | Oxazepam | Tyramine |
| Digoxin | Oxolinic acid | D, L-Tyrosine |
| Diphenhydramine | Oxymetazoline | Uric acid |
| Doxylamine | Papaverine | Verapamil |
| β-Estradiol | Penicillin-G | Zomepirac |
| Estrone-3-sulfate | Pentazocine | |

## 【ALCOHOL PERFORMANCE CHARACTERISTICS】

The detection limit on the **Oral Fluid Alcohol Rapid Test** is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the **Oral Fluid Alcohol Rapid Test** can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

## 【ALCOHOL ASSAY SPECIFICITY】

The **Oral fluid Alcohol Rapid Test** will react with methyl, ethyl and allyl alcohols.[19]

## 【ALCOHOL INTERFERING SUBSTANCES】

The following substances may interfere with the **Oral fluid Alcohol Rapid Test** when using samples other than oral fluid. The named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test.

A. Agents which enhance color development
- Peroxidases
- Strong oxidizers

B. Agents which inhibit color development
- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid.
- Bilirubin

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### Index of Symbols

| | | | | | |
|---|---|---|---|---|---|
| | Consult instructions for use | | Contains sufficient for <*n*> test | EC REP | Authorized representative in the European Community/European Union |
| IVD | *In vitro* diagnostic medical device | | Use-by date | | Do not reuse |
| | Store between 2-30 °C | LOT | Batch code | REF | Catalogue number |
| | Do not use if package is damaged and consult instructions for use | | Manufacturer | | |


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